Remarks

Information Disclosure Statement

The applicant did not receive from the examiner an initialed copy of the Information Disclosure Statement filed with the application and the references cited in the International Search Report. The examiner is respectfully requested to initial the Information Disclosure Statement to indicate that the examiner has considered the references cited in accord with MPEP § 609 and provide a copy of the initialed document for the applicant's files.

Status of the Claims

Claims 1-11 are pending in the application and have been rejected.

Explanation of the Amendments

The amendment to the specification is made to provide a "Brief Description of the Drawings" as requested by the examiner.

Minor revisions have been made to the wording of claim 1 to improve clarity. No change in the scope of the claim is intended thereby.

In claim 2 the amendment to specify the "given" peptide has been made to improve clarity. The term "long peptide" has been replaced by "peptide which comprises at least 20 amino acid residues". Basis for the amendment can be found on p.4 first paragraph, and also p.5, final paragraph.

Claims 4, 5, 9 and 10 have been reworded to improve clarity.

Response to the Specification Objection

The examiner objects that the specification does not contain a heading "Brief Description of the Drawings" in the disclosure (citing 37 C.F.R. § 1.74). The applicant respectfully points out that the specification met the requirements of 37 C.F.R. § 1.74 since the required brief

description of the drawings was provided on p. 8 lines 1-6, and there is no requirement for a heading "Brief Description of the Drawings" be used. However, in order to expedite prosecution, applicant herein amends the specification to insert appropriate paragraphs identified as a "Brief Description of the Drawings". The inserted text is reproduced from that provided on p. 8 lines 1-6.

Response to the Claim Rejections.

The examiner has rejected claims 1-11 under 35 U.S.C. § 112 second paragraph for alleged indefiniteness. The examiner states that claim 1 is indefinite because the method steps result in a peptide bound at its C-terminal end to a second resin and it is allegedly not clear whether it is intended to have the peptide remain upon or be cleaved from the resin. Claims 2-11 are said to be indefinite because they depend from claims 1. The applicant respectfully traverses the rejection.

The examiner is respectfully reminded that the definiteness requirement of 35 U.S.C. § 112 is satisfied by "claims which define the patentable subject matter with a *reasonable* degree of particularity and distinctness." MPEP 2173.02 (emphasis in the original). Applicants are entitled to "latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire" *Id.* Further,

> [d]efiniteness of claim language must be analyzed, not in a vacuum, but in light of:
>
> (A) The content of the particular application disclosure;
> (B) The teachings of the prior art; and
> (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made."

Id.

The applicant respectfully submits that the claim is clear as written. As the examiner points out, carrying out the steps of claim 1 results in the synthesis of a peptide bound at its

terminal end to the second resin. The person skilled in the art would recognize that a peptide has been synthesized whether or not it is cleaved from the resin at the conclusion of the synthesis steps recited in claim 1, and that therefore claim 1 recites all the essential steps of the peptide synthesis. The person skilled in the art would recognize that although the essential steps of claim 1 are complete when the synthesis of the peptide is completed on the solid phase that the peptide may optionally subsequently be cleaved from the solid phase. Having these alternative possibilities does not render the claims unreasonably indefinite.

Further, the existence of alternative possibilities as to whether the peptide remains upon or is cleaved from the solid phase following completion of its synthesis does not cause incongruity between the use of the term "given peptide" in the preamble and in step (d). This is because the person skilled in the art would recognize a peptide of a given sequence as being the same peptide whether or not the peptide was bound to or cleaved from the solid phase (indeed, the examiner refers to the possibilities of "the peptide" remaining on, or being cleaved from the resin).

In view of the foregoing, it respectfully submitted the reasons given by the examiner for rejecting claim 1 do not demonstrate that claim 1 fails to describe claimed subject matter with a reasonable degree of particularity and distinctness, and that the rejection of claims 1-11 for alleged indefiniteness should be withdrawn.

The examiner also rejected claim 2 under 35 U.S.C. § 112 second paragraph for alleged indefiniteness. The examiner was of the opinion that the term "long peptide" in claim 2 was insufficiently precise. It is believed that the amendment of claim 2 to replace the term "long peptide" with "peptide which comprises at least 20 amino acid residues" overcomes the rejection, and that, consequently, the rejection of claim 2 may be withdrawn.

The examiner also rejected claim 9 under 35 U.S.C. § 112 second paragraph for alleged indefiniteness. The examiner was of the opinion that the specification indicated that the applicant intended to claim (a method for the synthesis of) a "long peptide" wherein the peptide

was required to be at least 20 amino acid residues long and that the claim should be corrected to define a lower limit for the length of the "given peptide". The applicant respectfully traverses the rejection.

In the specification at p. 5, it is stated that:

> Whilst peptides of any length can be synthesised using the method of the invention, the method is particularly suited for the synthesis of peptides having at least 20 amino acid residues or "long peptides". The method is particularly suitable for peptides having up to about 150 amino acid residues.

When the specification refers to the method being suitable for peptides "having up to about 150 amino acid residues" no limitation to "long peptides" can be inferred. To the contrary, the specification explicitly states that "peptides of any length can be synthesised using the method of the invention". Thus, there is no need for the applicant to make a "correction" to claim 9 to specify a lower limit on the length of the peptide synthesized in the claimed method. It is respectfully submitted that the rejection of claim 9 is incorrect and should be withdrawn.

The examiner has rejected claim 11 under 35 U.S.C. § 112 second paragraph for alleged indefiniteness. The examiner stated that the limitation "wherein the C-terminal portion is fully protected so it can be attached onto the second resin" rendered the claim unclear because it is allegedly not clear how a peptide with a C-terminal proline can attach to a resin when the peptide's C-terminus is protected and the poline residue does not have any side-chain functionality to attach to the second resin. The applicant respectfully traverses the rejection.

As pointed out above, the definiteness requirement of 35 U.S.C. § 112 is satisfied by "claims which define the patentable subject matter with a *reasonable* degree of particularity and distinctness." MPEP 2173.02 (emphasis in the original). Further,

> [d]efiniteness of claim language must be analyzed, not in a vacuum, but in light of:
>
> (A) The content of the particular application disclosure;

> (B) The teachings of the prior art; and
> (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made."

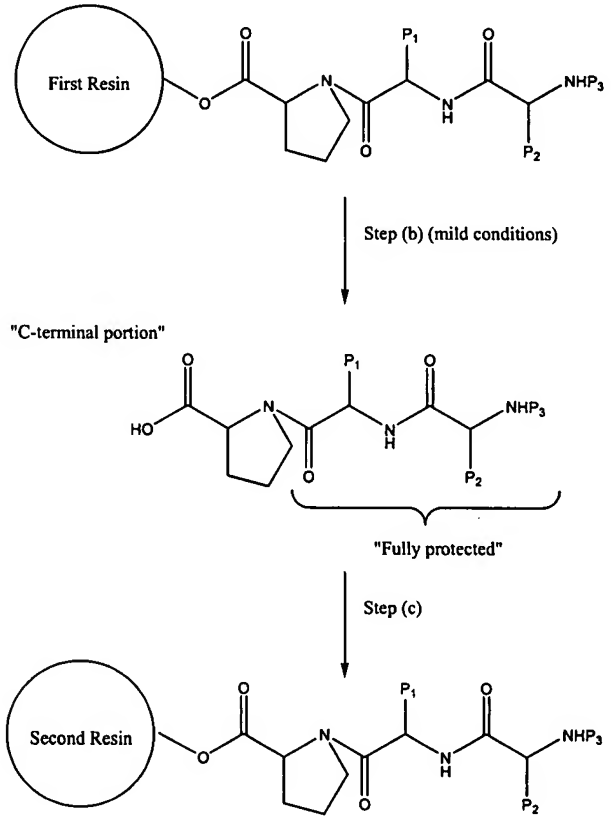
Id.

In making the rejection of claim 11, it is respectfully submitted that the examiner has not fully considered the content of the application disclosure and the claim interpretation that would be given by the person skilled in the art to the term "wherein the C-terminal portion is fully protected". The meaning of claim terms must be interpreted in view of the specification. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1321 (Fed. Cir. 2005) (en banc) ("Properly viewed, the 'ordinary meaning' of a claim term is its meaning to the ordinary artisan after reading the entire patent.") In the specification on p. 7 starting at line 17, it is stated:

> Advantageously, the cleaving step from the first resin is achieved using a mild acid treatment, for example 20% trifluoroethanol in dichloromethane. This allows a fully protected (tri-) peptide moiety to be obtained. Thus, the C-terminal portion can be provided fully protected so it can be coupled directly onto the resin suitable for synthesis of a long peptide. The protective groups may be the standard protective groups usually used in Fmoc (9-fluorenylmethoxycarbonyl), Nsc (2-(4-nitrophenylsulfonyl)ethoxycarbonyl) or t-Boc (ter-butyloxycarbonyl) peptide synthesis.

Given the context of this disclosure, the reference to the "C-terminal portion" being "fully protected" clearly does not mean that the C-terminal carboxyl group is protected. Rather, where the specification refers to the "C-terminal portion" being "fully protected" it is clear that this means that the cleaving step described in step (b) of claim 1 is performed under mild conditions such that cleavage of the C-terminal portion from the resin occurs without disturbing other protecting groups present (i.e. on the peptide side-chains of the C-terminal portion). The C-terminal portion is thus fully protected other than at the C-terminal carboxyl group, which, as noted by the examiner, is required to be unprotected for attachment to the second resin.

This may be illustrated by the following Scheme, illustrating Steps (b) and (c) of claim 1 as limited in claim 11. In the Scheme, for the purposes of illustration, a tripeptide is shown as having been synthesized as the proline-containing C-terminal portion. The tripeptide has a C-terminal proline to which are attached, in sequence, an amino acid with a protected side-chain (P_1) and an amino acid with a protected side chain (P_2) having N-terminus protected by a protecting group P_3. When the cleavage step (step (b) of claim 1) is carried out under mild conditions, as described in the specification on p. 7, the cleavage from the resin may be effected without disturbing the protecting groups of the protected side-chains (P_1 and P_2) or the N-terminal protecting group (P_3). When the cleaved peptide ("the C-terminal portion") is provided in step (c) for reattachment to the second resin, the protecting groups of P_1 and P_2 and protecting group P_3 are intact such that the "C-terminal portion" is provided "fully protected" for step 3.



Scheme

The person skilled in the art would recognize, based upon the explanation provided in the specification, that the term "fully protected so it can be attached directly onto the second resin" means, as illustrated above, that the "C-terminal portion" is protected at all positions other than the C-terminal carboxyl group, such that it the reattachment step of step (c) can be performed selectively at the C-terminal carboxyl group without competing reactions of the side-chains lacking protecting groups.

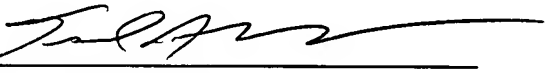
Based upon the foregoing, it is respectfully submitted that the meaning of "C-terminal portion is fully protected" in claim 11 is clear, and that the claim is therefore not indefinite. It is therefore respectfully requested that the rejection of claim 11 for alleged indefiniteness be withdrawn.

Conclusion

Since the examiner has found the claims to be free of the art, and the above remarks have demonstrated the examiner's grounds of rejection to have been overcome, it is respectfully submitted that the claims are in condition for allowance. An early action toward that end is therefore earnestly solicited.

Respectfully submitted,

ANDREW SMITH JOHNSTONE STEWART

BY 

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